The Dilemma of ICD Implant Testing

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Ventricular fibrillation (VF) has been induced at implantable cardioverter defibrillator (ICD) implant to ensure reliable sensing, detection, and defibrillation. Despite its risks, the value was self-evident for early ICDs: failure of defibrillation was common, recipients had a high risk of ventricular tachycardia (VT) or VF, and the only therapy for rapid VT or VF was a shock. Today, failure of defibrillation is rare, the risk of VT/VF is lower in some recipients, antitachycardia pacing is applied for fast VT, and vulnerability testing permits assessment of defibrillation efficacy without inducing VF in most patients. This review reappraises ICD implant testing.

At implant, defibrillation success is influenced by both predictable and unpredictable factors, including those related to the patient, ICD system, drugs, and complications. For left pectoral implants of high-output ICDs, the probability of passing a 10 J safety margin is ∼95%, the probability that a maximum output shock will defibrillate is ∼99%, and the incidence of system revision based on testing is ≤5%. Bayes’ Theorem predicts that implant testing identifies ≤50% of patients at high risk for unsuccessful defibrillation. Most patients who fail implant criteria have false negative tests and may undergo unnecessary revision of their ICD systems. The first-shock success rate for spontaneous VT/VF ranges from 83% to 93%, lower than that for induced VF. Thus, shocks for spontaneous VT/VF fail for reasons that are not evaluated at implant. Whether system revision based on implant testing improves this success rate is unknown. The risks of implant testing include those related to VF and those related to shocks alone. Vulnerability testing reduces risks related to VF, but not those related to shocks. Mortality from implant testing probably is 0.1–0.2%. Overall, VF should be induced to assess sensing in ∼5% of ICD recipients. Defibrillation or vulnerability testing is indicated in 20–40% of recipients who can be identified as having a higher-than-usual probability of an inadequate defibrillation safety margin based on patient-specific factors. However, implant testing is too risky in ∼5% of recipients and may not be worth the risks in 10–30%. In 25–50% of ICD recipients, testing cannot be identified as either critical or contraindicated.

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implantable cardioverter-defibrillator, defibrillation threshold, defibrillation

For 25 years, the accepted method for implantable cardioverter-defibrillator (ICD) implantation has included induction of ventricular fibrillation (VF) to ensure that the ICD will sense, detect, and defibrillate VF. Occasionally, it causes complications, and rarely, death. In the early era of less efficient ICDs, the value of defibrillation testing seemed self-evident. Today, better understanding of defibrillation, improved technology, and use of ICDs for primary prevention of ventricular tachycardia (VT) or VF have led some to question the need for either defibrillation testing or any assessment of defibrillation efficacy at ICD implantation.1,2

This review has four goals: (1) summarize the purpose and methods of implant testing; (2) review the benefits, risks, and clinical utility of implant testing; (3) consider specific “how to” aspects of ICD implantation, including how to approach the patient in whom defibrillation is unreliable and how to minimize risk; and (4) provide a perspective on when implant testing is indicated and when it is not. It is intended to complement previous works that address defibrillation testing,3–6 vulnerability testing,7 and the approach to the patient who is difficult to defibrillate.8

Background

VF is induced at ICD implantation to assess: (1) electrical integrity of the connections between leads and pulse generator; (2) reliable sensing, detection, and redetection in VF; and (3) optimal, or at least adequate, programmed shock strength.
Low voltage pulses or shocks in normal rhythm can achieve the first goal. This review addresses the second goal briefly and then focuses on the third.

**Sensing and Detection of VF**

For testing, maximum sensitivity often is programmed to an insensitive setting (∼1 mV). Reliable sensing of VF at this setting ensures an adequate safety margin either for sensing of “fine” VF with nominal sensitivity (∼0.3 mV) or for programming a less sensitive setting to avoid T-wave oversensing. Sensing and redetection of VF after unsuccessful defibrillation is the most difficult case for detection of VF. Early-model, integrated bipolar leads with short tip-coil spacing (e.g., 6 mm) were prone to post-shock undersensing. Post-shock redetection of VF may be tested if a chronically-implanted system uses such an electrode. With the advent of dual-chamber ICDs, few patients have separate pacemakers, but some have other separate devices, such as neurostimulators, and those designed to modulate cardiac contractility by non-excitatory electrical stimulation. In these patients, specific testing is required to avoid device–device interactions. The most important of these is failure to sense VF due to resetting of auto-adjusting sensitivity or automatic gain control by the electrical stimuli from the other device. In dual-chamber ICDs, detection of VF may be delayed or prevented by “intra-device” interactions, such as one caused by ventricular blanking periods related to rate-smoothing pacing.

Several studies demonstrate a strong correlation between R wave amplitude in native rhythm and reliable sensing during induced and spontaneous VF. If the R wave during native rhythm or atrial pacing is ≥5–7 mV, sensing during VF is almost always sufficient to ensure rapid detection. With modern ICDs, undersensing of spontaneous VF despite an adequate R wave in baseline rhythm is extremely rare. It usually occurs in one of two circumstances: either transient effects that slow VF and reduce the slew rate of local electrograms (e.g., ischemia, drug, or hyperkalemia) or rapidly-varying electrogram amplitude in VF. Unfortunately, neither type of undersensing is reproducible in the electrophysiology lab.

**How Should Shock Strength be Measured?**

The shock waveform parameter that most directly influences defibrillation is voltage as a function of time (duration). The physics of capacitive-discharge waveforms links the energy stored in the ICD’s capacitor to the voltage and duration of the delivered waveform. Although shock energy is not a direct measure of shock effectiveness, it is so widely cited as a measure of shock strength that we follow convention and use it unless otherwise indicated.

**Probabilistic Nature of Defibrillation**

While defibrillation may be deterministic on a microscopic level, it is probabilistic on a macroscopic level. Thus, clinical defibrillation is usually described by a probability-of-success curve with shock strength on the abscissa and probability of successful defibrillation on the ordinate (Fig. 1). The result of a series of defibrillation test shocks at the same shock strength gives an estimate of the probability of success at that shock strength. Multiple series of test shocks at different shock strengths are required to provide an estimate of the defibrillation probability-of-success curve. The defibrillation probability-of-success curve is usually displayed as a logistic regression curve, although it may be better represented by one in which the probability of success remains at zero for very weak shocks, rises steeply from zero, and then approaches 100% asymptotically.

**The Implant Criterion**

Determination of a complete defibrillation probability-of-success curve for an individual patient requires more fibrillation–defibrillation episodes than is practical or safe in humans. Thus more limited implant criteria have been developed. The fundamental principle of...
defibrillation implant testing is illustrated in Figure 2. Defibrillation efficacy is assessed at one or more shock strengths. Usually, VF is induced one or more times, and each episode of VF is defibrillated at one or more shock strengths. The outcome of each defibrillation shock is classified as either successful or unsuccessful. Alternatively, testing based on the upper limit of vulnerability (ULV) may be used to assess defibrillation efficacy without inducing VF in most patients. In this type of testing, shocks are delivered at the most vulnerable time in the cardiac cycle. A shock strength is considered sufficient for defibrillation if VF is not induced and insufficient if VF is induced.

Whatever the method of testing, the sequence of outcomes is compared with the implant criterion, which is the level of defibrillation performance at implant that is predicted to result in a clinically adequate success rate for defibrillation of spontaneous VF. Performance that does not meet the implant criterion requires revision of the ICD system, comprising the leads and pulse generator.

In evaluating both the weight of the evidence supporting various implant criteria and the applicability of this evidence to present clinical practice, it is useful to consider the genesis of the most widely used criterion, reliable defibrillation at 10 J below the ICD’s maximum output. This criterion is based on a post-hoc analysis performed in 33 patients treated with monophasic, epicardial ICDs. In this retrospective analysis, the independent variable was the difference between an ICD’s maximum output and the step-down (or up) DFT. The dependent variable was defibrillation of induced VF at post-operative electrophysiological study. Overall, maximum output (28 J) shocks were successful in 29 patients (88%). A maximum output shock succeeded in all 19 patients (100%) with a safety margin of ≥10 J, but in only 10 of 14 patients (71%) with a safety margin < 10 J (P < 0.04).

The Defibrillation “Threshold” (DFT)

In physiology, a threshold stimulus is the minimum stimulus required to evoke a response. Stimuli weaker than the threshold never evoke a response, and stimuli stronger than the threshold always evoke a response. Often, the strength of the response increases as the stimulus strength increases beyond the threshold value.

The threshold concept does not apply to defibrillation. The probabilistic nature of defibrillation ensures that, over the clinically relevant range of shock strengths, the same shock strength may either succeed or fail on successive attempts. Further, with rare exceptions, the strength of the defibrillation response does not increase with increasing stimulus strength; either the stimulus defibrillates or it does not.

Nevertheless, the term DFT, used as early as 1963, is deeply established in the defibrillation literature as the minimum shock strength that defibrillates. Historically, it has been used as a patient-specific measure of defibrillation efficacy, and a DFT below a specific value has been used as a patient-specific implant criterion. Given the probabilistic nature of defibrillation, it is not surprising that clinical measurement of DFT has only fair reproducibility. In one study of 25 patients, the correlation coefficient between two successful determinations of the DFT was 0.64. Two patients (8%) had differences between first and second determinations of ≥10 J.

Different methods of measuring the DFT approximate different points on the probability-of-success curve. The error of estimating a point on the probability-of-success curve is a nonlinear

**Figure 2.** Role of the implant criterion. The implant criterion is the level of defibrillation performance predicted to result in a clinically adequate success rate for defibrillation of spontaneous VF. The implant criterion results in a true positive result when patients who have reliable defibrillation of spontaneous VT/VF pass the test. In a false positive result, patients who have unreliable defibrillation of spontaneous VT/VF fail the implant criterion and may undergo indicated ICD system revision or retesting at a later date. In a false negative result, patients who have unreliable defibrillation fail the implant criterion and undergo unnecessary system revision or retesting, with their associated risks.
Commonly used methods for assessing defibrillation efficacy at implant of an ICD with a maximum shock strength of 30 J. The top two panels and the bottom left pane illustrate protocols to determine the patient-specific DFT. The bottom right panel illustrates a method to verify a defibrillation safety margin between the maximum shock strength of the ICD and the shock strength required for consistent defibrillation. In each panel, diamonds indicate initiation of VF, “s” indicates defibrillation success, and “f-resQ” indicate defibrillation failure followed by a strong rescue shock. The rescue shock may be delivered internally from the ICD or externally from a transthoracic defibrillator. The top left panel illustrates the Step Down method in which each failed shock is followed by a rescue shock. Thus each fibrillation-defibrillation episode provides data regarding the efficacy of 1 shock strength. The bottom left panel illustrates the Step Up method. Because multiple shock strengths are tested during a single episode of VF, this method is quicker than either of the other two DFT methods. Limited available data indicate that the efficacy of a defibrillation shock is not influenced significantly by delivery of a preceding shock if the duration of VF is less than 15–20 sec. The potential for long episodes of VF is a concern regarding this method. The top right panel illustrates the Binary Search method. The number of fibrillation-defibrillation episodes is fixed in the Binary Search method, but variable in the Step Up and Step Down methods. The Binary Search method is designed to estimate the E50. Conceptually, the Step Down method is more likely to result in a DFT greater than the E50 because it provides multiple opportunities for shocks stronger than the E50 to fail. In contrast, the Step Up method is more likely to result in a DFT less than the E50 because it provides multiple opportunities for shocks weaker than the E50 to succeed. The magnitude by which the Step Up and Step Down DFTs deviate from the E50 depends on the starting shock strength and step size; in clinical practice, it may be small. The bottom right panel illustrates the Safety Margin method. This method limits testing to the minimum necessary to determine if there is a sufficient safety margin between the maximum shock strength of the ICD and the shock strength required for consistent defibrillation. LED indicates lowest tested energy that defibrillates. This method determines a DFT only if the DFT exceeds the tested shock strength. In all methods, the ICD system is modified if a 10-J safety margin is not achieved. The figure does not illustrate the point that success or failure of an internal rescue shock from the ICD may provide incremental information about defibrillation efficacy of the ICD system.

The most commonly used clinical DFT methods include binary search, step down, and step up (see Figure 3). The binary search method approximates the E50. The widely used, step-down DFT approximates the E50 to E70, depending on the starting shock strength and step size; and the step-up DFT approximates the E30 to E50, depending on the starting shock strength and step size. Because step-up methods result in longer VF episodes if multiple shocks are required for defibrillation, some investigators are concerned about their safety. On the other hand, they permit assessing more shock strengths with fewer episodes of VF. In clinical practice, the binary search method gives similar results to the step-down and step-up methods.
Other protocols require two or three consecutive defibrillation successes to define “enhanced” thresholds referred to as the DFT+ and DFT++, respectively. They correspond to higher points on the probability-of-success curve than the DFT. In practice, the term DFT is used as a shorthand to mean an estimate of a point on the patient’s defibrillation probability-of-success curve.

Patient-Specific Versus Safety-Margin Implant Criteria

Both “patient-specific” and “safety-margin” implant criteria have been applied. Patient-specific criteria attempt to identify the minimum shock strength that defibrillates reliably so that ICD first shocks can be programmed to the lowest effective shock strength. Safety-margin criteria limit testing to the minimum number of induced episodes necessary to determine if there is a sufficient safety margin between the maximum shock strength of the ICD and the shock strength required for consistent defibrillation.

The objective of a patient-specific implant strategy is an accurate estimate of shock strength that corresponds to a high probability of successful defibrillation (e.g., E95). Patient-specific criteria are intended to minimize the long-term potential adverse effects of excessive programmed shock strength.

A safety-margin strategy is preferred when the principal goal is to minimize the risks of shocks and fibrillation-defibrillation testing. After safety-margin testing, the first shock usually is programmed to maximum output. Generally, safety-margin criteria are appropriate whenever a patient specific safety-margin is judged unnecessary.

Defibrillation Testing

Methods for defibrillation testing have been described in detail. Briefly, VF is induced one or more times by rapid pacing, direct current, or T-wave shocks; defibrillation test shocks of varying strength are delivered; and the outcome (success or failure) of the defibrillation shock or sequence of shocks is compared with the implant criterion.

In patient-specific testing, the success or failure of the first test shock usually determines the programmed strength of the next test shock: If the first test shock defibrillates, the strength of the next test shock is reduced. Alternatively, if the first test shock does not defibrillate, a stronger rescue shock is delivered, and the strength of the next test shock is increased. After a fixed or variable number of fibrillation-defibrillation episodes, a determination is made as to whether the ICD system passes or fails the implant criterion. In safety-margin testing, the outcome of the first defibrillation shock may or may not alter the strength of the second shock.

Rescue shocks may be delivered internally through the ICD electrodes or externally through self-adhesive defibrillation electrodes placed prior to the procedure. Internal rescue shocks avoid skin burns associated with external shocks. Their success or failure provides incremental information about the performance of the ICD lead system. However, they are delayed by the times required for redetection of VF (unless delivered in the “commanded shock” mode) and for charging the ICD capacitor and may thus result in longer VF episodes.

Interpreting Defibrillation Testing: Regression to the Mean

Assessment of defibrillation efficacy at ICD implantation must take the probabilistic nature of defibrillation into consideration. A defibrillation failure may be a low-probability event due to chance alone, not evidence of substandard defibrillation performance. For example, a defibrillation system with an acceptable 95% success rate at implant testing is expected to fail to defibrillate in 5% of attempts. If a shock at the E95 fails to defibrillate, defibrillation of a second episode of VF at the same shock strength is likely to succeed, since it has the same 95% probability of success. To generalize, when a single measurement falls in the tails of a statistical distribution (i.e., an unlikely defibrillation failure occurs), a repeat measurement will likely be closer to the mean. This behavior, called regression to the mean, is characteristic of parameters having a normal distribution.

The clinical implication is that an ICD system should not be revised after a single defibrillation failure without other evidence that the tested shock strength is insufficient. If a system is revised after a single failure, success of a subsequent shock may merely represent regression to the mean: The system is exhibiting typical performance rather than improved performance.

Statistical Modeling of Defibrillation Testing

Statistical modeling based on a family of estimated defibrillation probability-of-success curves for individual patients may be used to circumvent the limitations of implant criteria based on one or a few shocks. As a first step, each patient’s curve is generated using logistic regression performed on a data set consisting of the few, dichotomous outcomes of the defibrillation shocks delivered at ICD implant. Often, only one shock is delivered at each shock strength, so that the calculated probability of success is either 0 or 100%. For example, if a step-down defibrillation protocol is performed with successes at 20 and 15 J and a failure at 10 J, the probability of success is calculated to be 100%
at 20 J, 100% at 15 J, and 0% at 10 J. But there is a reasonable chance that the true probability of success at 15 J might be 80% and some chance that it might be 50% or lower. Similarly, there is a reasonable chance that the true probability of success at 10 J might be 20% and some chance that it might be 50% or higher.

Even if the same shock strength is tested more than once, the confidence in a single curve is limited by the sparseness of data available from each patient. Statistical modeling can be used to construct a probability-of-success curve that takes into account both the individual patient’s defibrillation data and the pooled results from the population as a whole. The result is a family of curves representative of the population of patients.32,57,58 (see Fig. 4).

Smits and DeGroot provided a comparison of the ability of different implant criteria to identify patients with \( P_{\text{min}} \geq 90\% \).59 In a sample population in which 94% of patients had the required minimum shock efficacy, the specificity of failing high DFT patients varied from 11% for a binary search protocol requiring DFT \( \leq 24 \) J to 74% for a step-down protocol requiring DFT \( \leq 18 \) J. As expected, implant criteria had an inverse relationship between specificity of failing high DFT patients and sensitivity for passing low DFT patients. The two criteria mentioned above had sensitivities of 100% and 91%, respectively. There was little difference in sensitivity and specificity between requiring two successes at 24 J and a single success at 15 J. Table I shows sensitivity and specificity of various implant criteria.

**Predictive Value of Defibrillation Testing**

Assessing the value of defibrillation testing requires considering four questions: (1) Does it
Table I.

Predicted Performance of Different Implant Criteria

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Criterion</th>
<th>% Passing</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 inductions</td>
<td>2/2 successes at 24 J</td>
<td>93</td>
<td>96</td>
<td>53</td>
</tr>
<tr>
<td>1 induction</td>
<td>1/1 success at 15 J</td>
<td>91</td>
<td>94</td>
<td>52</td>
</tr>
<tr>
<td>1 induction</td>
<td>1/1 success at 12 J</td>
<td>87</td>
<td>90</td>
<td>61</td>
</tr>
<tr>
<td>Step down</td>
<td>DFT ≤ 24 J</td>
<td>96</td>
<td>98</td>
<td>32</td>
</tr>
<tr>
<td>Step down</td>
<td>DFT ≤ 18 J</td>
<td>87</td>
<td>91</td>
<td>74</td>
</tr>
<tr>
<td>Binary search</td>
<td>DFT ≤ 24 J</td>
<td>99</td>
<td>100</td>
<td>11</td>
</tr>
<tr>
<td>Binary search</td>
<td>DFT ≤ 12 J</td>
<td>87</td>
<td>90</td>
<td>61</td>
</tr>
</tbody>
</table>

predict shock success for induced VF? (2) Does it predict shock success for spontaneous VT/VF? (3) What is the relationship between defibrillation testing and conversion of spontaneous ventricular tachyarrhythmias, including antitachycardia pacing? (4) Does it predict total mortality or sudden death?

Bayes’ Theorem and the Implanter’s Dilemma

Bayes’ theorem of conditional probability theory combines the a priori estimate of the probability that a condition is present with measures of test performance to derive an a posteriori estimate.60 The test in question is the implant criterion. The condition being estimated is the probability of successful defibrillation at a given shock strength for either induced or spontaneous VF.

Bayes’ theorem shows that testing provides limited incremental information if the a priori probability is very high or very low. For modern left pectoral ICDs and high-output pulse generators, the probability of passing a 10-J safety margin is sufficiently high (95%) that testing provides little incremental information. The Bayesian analysis in Fig. 5 shows that implant testing identifies only one third to one half of patients at high risk for failed defibrillation. Most patients who fail the implant criteria do so because of false negative tests.32 Although rigorous testing recommends unnecessary system revision in a significant minority of patients, occasional implant testing results in a system revision that saves a patient’s life. This is the implanter’s dilemma.

Prediction of Shock Success for Induced VF

Table II shows that passing patient-specific implant criteria results in an extremely high success rate for defibrillation of induced VF either at maximum output or the programmed shock strength. The LESS trial, performed in patients who had DFTs ≤15 J, applied a strict, patient-specific implant measure referred to as the DFT+++, defined as the weakest shock strength that defibrillated on three consecutive trials.52 At implant, the defibrillation success rate was 91% for shocks at the DFT+++ and >99% for shocks 4–6 J above the DFT+++ . Data from multiple studies confirm that a single defibrillation success at 10–15 J predicts shock success for stronger (20–31 J) shocks with an accuracy of ~99% .36,53,65 On the other end of the spectrum, the SCD-HeFT trial specified ICD implant even if no defibrillation success was achieved during testing.66 All patients were reported to have successful defibrillation at implant with shocks ≤30 J. Thus first shock success rates at either patient-specific programmed shock strengths or maximum output defibrillate induced VF in nearly 100% of ICD recipients.

Prediction of Shock Success for Spontaneous Arrhythmias in the VF Zone

The VF zone of ICDs is a rate or cycle length-based zone that includes all arrhythmias with cycle lengths shorter than a boundary value between about 320 ms and 240 ms. Most studies report shock success rates for all VT/VF within that zone,32,67–69 while one study reports separate results for polymorphic and monomorphic VT.65 Table III shows that first shock success rates for spontaneous rapid VT or VF range from 83% to 93%,32,67–69 lower than rates reported for induced VF.

This consistent observation suggests that shocks for spontaneous VT/VF fail for reasons that are not evaluated at implant. This is not surprising: Defibrillation testing is performed on sedated patients after clinical variables have been optimized. In contrast, spontaneous VT/VF occur in a less “controlled” environment that may include variations in multiple variables known to reduce defibrillation efficacy: autonomic tone,71 ischemia,72,73 hyperkalemia,74 exacerbation of heart failure, drugs prescribed in follow-up (see following), or progression of cardiac disease.75 DFTs are also higher in the upright than supine
in about 60% of ICD recipients. Second, ICDs deliver up to six shocks for VT/VF so that subsequent shocks may succeed if the first fails.

Prediction of Sudden Death and Total Mortality

The central question for this review is whether better implant testing can reduce sudden cardiac death and total mortality in ICD patients. Meta-analyses of randomized clinical trials indicate that ICD therapy reduces the risk of sudden cardiac death by about 60%. The two largest studies of post-mortem interrogation of ICDs indicate that 25% sudden deaths in ICD patients were caused by failure to defibrillate VF. However, VT/VF is the presenting rhythm in most episodes of sudden cardiac death in ICD patients. Post-defibrillation electromechanical dissociation accounted for 29% of these deaths, and multiple shocks were required to defibrillate VF in many of these episodes. These data indicate that failure to defibrillate spontaneous VF remains a major cause of sudden death in ICD patients and suggest that failure to defibrillate promptly may be equally or more important. However, data regarding the relationship between modern ICD implant criteria and either total mortality or arrhythmic death are both limited and difficult to interpret. Pires et al. reported that the first ICD therapy was unsuccessful on at least one occasion in 9 of 14 patients (64%) whose terminal event was VT/VF; and 6 of these patients had inadequate first-shock safety margins. In an older study of monophasic, thoracotomy ICDs with DFTs ≥25 J, Epstein et al. reported an actuarial rate of sudden arrhythmic death of 16% of patients over 5 years, but the relevance of these data to biphasic-waveform, tiered-therapy ICDs is uncertain. DeSouza et al. reported that not passing a 10-J safety-margin implant criterion was independent predictor of sudden cardiac death in biphasic waveform, transvenous ICDs. But Shukla et al. reported no correlation between DFT and either total mortality or sudden cardiac death.

It will be difficult to develop a meaningful relationship between ICD implant testing and arrhythmic death in patients who undergo ICDs for primary prevention for at least three reasons. (1) Given the present a priori probabilities at implant testing, about half of patients who “fail” implant criteria do so because of false negative tests. They would be expected to have successful defibrillation shocks. (2) With the widespread use of antitachycardia pacing, the annual incidence of appropriate shocks is only 5–10% per year. (3) Factors that cannot be tested at implant probably cause some failed shocks or sudden death. Such factors include ischemia, progressive heart failure, metabolic abnormalities, drug effects, and ICD lead or generator failures. Even if such a relationship

Figure 5. Bayesian analysis of defibrillation testing. The percent of patients with a successful maximum output shock is plotted on the ordinate. The first column shows data from 1999 in which the success rate for maximum output shocks was 85% for the first system tested. Subsequent columns assume that the success rate for maximum output shocks has increased to 95% in 2006 (see text and Table 2). Columns 3 and 4 show the performance of two implant criteria: a 10-J safety margin based on two consecutive successful shocks or four consecutive successful shocks. In the left two columns, values from top to bottom indicate the percent of patients who pass inappropriately and pass appropriately. In the right two panels, values indicate the percent of patients who fail inappropriately, fail appropriately, pass inappropriately, and pass appropriately. Testing identifies only one third to one half of the 5% of patients at high risk for failed defibrillation. Thus it provides limited incremental predictive value. The percent of patients who pass appropriately decreases from 95% for no testing to 89.7% for the more rigorous testing. Most patients who fail testing do so inappropriately.

Position. Durations of VT/VF duration greater than 15 sec may increase DFT. This is relevant either when undersensing occurs or when prolonged charge times occur due to aging effects on ICD batteries or failure to reform capacitors at adequate intervals. Another factor may be circadian variation in defibrillation efficacy. A morning peak in DFT corresponds to a morning peak in failed first shocks for spontaneous VT/VF.
Table II.
Acute Defibrillation Success with Pectoral ICDs

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Study Type</th>
<th>ICD Output (J)</th>
<th>10 J Safety Margin (No Revision)</th>
<th>Maximum Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCD-HeFT</td>
<td>716 (85%)</td>
<td>1st prevention prospective (left sided)</td>
<td>30</td>
<td>–</td>
<td>100%</td>
</tr>
<tr>
<td>Russo et al.</td>
<td>1137</td>
<td>1½/2 prevention retrospective</td>
<td>no revision</td>
<td>various</td>
<td>94%*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100% with revision</td>
<td></td>
</tr>
<tr>
<td>Toal et al.</td>
<td>551</td>
<td>1st prevention retrospective</td>
<td>10 J safety margin</td>
<td>various</td>
<td>95.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>99.7% with revision</td>
<td></td>
</tr>
<tr>
<td>Sterns et al.</td>
<td>486</td>
<td>1½/2 prevention retrospective</td>
<td>no revision</td>
<td>30</td>
<td>93%</td>
</tr>
<tr>
<td></td>
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</table>

Three percent of revisions were change to high-output (≥34J) generator.

could be established, it will be even more difficult to determine which deaths might be prevented, except the minority caused by failure to convert VT/VF. Further, it will be difficult to unravel the question of how often a high DFT is caused by an inadequate ICD system, and how often it is an indirect marker of a “sicker” patient. Nevertheless, it is reasonable to accept the working hypothesis that patients with unreliable defibrillation at implant have a clinically unacceptable risk of sudden death.

Finally, some sudden cardiac deaths in ICD patients are caused by malfunctions of ICD leads or pulse generators.

Outcome of Defibrillation Testing

Modification of the ICD System

When transvenous, monophasic ICDs were introduced in the 1990s, implant testing commonly resulted in system modification, and ~10% required implantation of an epicardial lead system. However, with present active-can electrodes, efficient biphasic waveforms, and high-output (≥34 J) ICDs, implant testing rarely results in modifying the ICD system. For example, in a recent review of 1139 consecutive patients, defibrillation testing was performed in 95%. Of these, 3% had defibrillation safety margins <10 J despite use of high-output pulse generators. The incidence of system modification based on implant testing varies from 0–5% in recent studies.

Does Modification of the System Improve Clinical Care?

No study has tested the hypothesis that system modification improves clinical care. The required design of such a study raises ethical issues: Patients with unacceptable defibrillation safety margins would be randomized to system revision or no further operative modifications. Endpoints would include shock success for spontaneous VT/VF and mortality. In the era of transvenous, monophasic ICDs, the value of frequently performed system modification seemed self-evident. ICDs were implanted typically for drug-refractory sustained VT/VF, and the incidence of spontaneous VT/VF in ICD recipients was high. Because antitachycardia pacing was either not available or programmed infrequently for fast VT, termination of fast VT required a shock. There are numerous examples of patients with unacceptable defibrillation safety margins who died of failed defibrillation.

Presently, the probability of an inadequate defibrillation safety margin is low, the incidence of spontaneous VT/VF is lower in some primary prevention populations and antitachycardia pacing terminates most episodes of fast VT. Thus, if a study to assess the value of system modification were ethical, the required sample size would be larger than any previous ICD study.

Indirect evidence is limited. In one large study, there was no significant difference in long-term mortality between patients who required system modification to achieve an adequate safety margin versus those who did not (17% versus 20%, P = NS). This could be interpreted to mean that defibrillation testing improved clinical care by making the outcome of the initially “high DFT” group similar to the group who did not require modification. Alternatively, system revision may not have had any influence on outcome.

In two large, retrospective studies, the group of ICD recipients who did not undergo implant
defibrillation testing due to hemodynamic instability or severity of underlying heart disease had a higher total mortality than the group who underwent testing.\textsuperscript{61,67} One of these studies analyzed first-shock success rates for spontaneous device-detected VF and found no difference between the groups.\textsuperscript{67} Thus, observed difference in mortality are more likely related to differences in clinical factors such as severity of underlying heart disease and comorbidities than in whether or not defibrillation testing was performed.

In one study, total mortality was higher in patients with inadequate defibrillation safety margin than in the remaining patients, but there was no significant difference in the low incidence of sudden death (overall 4\% at 3 years). However, the small sample size of patients with inadequate defibrillation safety margin (n = 19) would not have permitted detection of a modest effect.\textsuperscript{100}

### Defibrillation Testing at Pulse Generator Replacement

The principal considerations at generator change are integrity of the lead system\textsuperscript{101} and possible changes in ICD safety margin since implant caused by progression of heart disease, changes in drug therapy, and possibly lead maturation. These latter considerations are discussed below. In a recent study, generator replacement or “upgrade” (to dual-chamber or cardiac resynchronization ICD) was an independent risk factor for system modification.\textsuperscript{61}

In some coaxial defibrillation leads, notably the Medtronic Model 6936 (Minneapolis, MN, USA), inner insulation failure may be undetected by standard noninvasive diagnostics and present as post-shock oversensing.\textsuperscript{102} Some defibrillation leads may provide sufficient dielectric to return a nominal lead impedance when assessed by a low voltage pulse, but they may fail catastrophically when a high voltage shock is delivered. Both these phenomena can be identified by a maximum output shock in normal rhythm without inducing VF. However, as noted previously, early-model, integrated bipolar lead with short tip-coil spacing (e.g., 6 mm) were prone to post-shock undersensing.\textsuperscript{9} Redetection of VF after an unsuccessful shock may be tested if a chronically-implanted system uses such an electrode.

Generally, defibrillation efficacy should be assessed (by either defibrillation or vulnerability testing) if the safety margin was low or not tested at implant, structural heart disease has progressed significantly, or drugs known to affect the DFT (e.g., amiodarone) have been added. If the patient has been clinically stable, testing may be

---

### Table III.
First Shock Success for Spontaneous VT/VF in VF Zone for Patients who Passed Implant Criteria

<table>
<thead>
<tr>
<th>Total Implant Programmed Spontaneous % Shock</th>
<th>Study Type</th>
<th>Implant Criterion</th>
<th>Programmed Shock (J)</th>
<th>Spontaneous VT/VF</th>
<th>% Shock Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>LESS\textsuperscript{52} 112 1/2 prevention prospective DFT++ ≤ 15 J 5 J &gt; DFT++ &gt;200 bpm</td>
<td>89.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LESS\textsuperscript{52} 184 1/2 prevention prospective DFT++ ≤ 15 J maximum (31 J) &gt;200 bpm</td>
<td>88.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PainFree Rx II\textsuperscript{69} 70 1/2 prevention prospective (left-sided) 10-J safety margin DFT++ 10-J &gt;250 bpm</td>
<td>87</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCD-HeFT\textsuperscript{68} 596 1 prevention prospective (left-sided) none maximum (variable) &gt;188 bpm</td>
<td>82.7</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterns et al.\textsuperscript{70} 70 1/2 prevention prospective (left-sided) 10-J safety margin maximum (30 J) polymorphic</td>
<td>93</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterns et al.\textsuperscript{70} 58 1/2 prevention prospective (left-sided) 10-J safety margin maximum (30 J) monomorphic &gt;200 bpm</td>
<td>83</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pires and Johnson\textsuperscript{67} 83 1/2 prevention retrospective 10-J safety margin DFT + 10-J VF zone</td>
<td>91</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pires and Johnson\textsuperscript{67} 243 1/2 prevention retrospective 10-J safety margin lowest shock tested + 10-J VF zone</td>
<td>91</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pires and Johnson\textsuperscript{67} 25 1/2 prevention retrospective none maximum VF zone</td>
<td>92</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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performed at the weakest previously tested successful shock strength. Alternatively, if cardiac status or drugs that alter the DFT have changed, a de novo safety margin strategy may be used.

Advantages of a High Defibrillation Safety Margin

Advantages of a Low DFT

A large defibrillation safety margin (e.g., DFT \( \leq \) 15 J) can be achieved in \~90% of ICD recipients with present technology, although system revision may be required in \~10% of patients.\(^{103-105}\)

Presently, excluding patients considered too sick to test, mean DFTs for fixed-tilt waveforms are in the range of 8–10 J for dual-coil leads and 10–12 J for single-coil leads, with standard deviations of about 4 J.\(^{103-105}\) A low DFT at the time of initial implantation may be a good defense against late increases in DFT.

Time-Dependent Increases in DFT

Early studies reported frequent increases in DFT during long-term follow-up of monophasic ICDs.\(^{106-108}\) Studies of patients with active-can biphasic waveform ICDs demonstrate lower DFTs at implant and a lower incidence of increased DFT over time,\(^{52,109-111}\) but increases that compromise defibrillation efficacy may occur in up to 15% of patients who are programmed to a 10-J safety margin.\(^{111}\) However, the standard deviation of DFTs also increases with time\(^{112}\) so that the increase is often greater for patients with higher initial DFTs. One study reported a clinically important rise in DFT in 17% of patients, with 3% requiring system revision.\(^{106}\) In another study, 6.5% of patients tested more than 1 year post-implant had failure of the first shock.\(^{113}\)

Drug-Dependent Increases in DFT

Post-implant addition of new drugs that may increase the DFT, chiefly amiodarone,\(^{114-118}\) is an important consideration. See “Drug Effects” on DFT later. ICD patients are often treated with noncardiac drugs. These drugs usually are withheld at the time of ICD implantation, and little is known about their effects on defibrillation efficacy post-implant. However, one report indicates that sildenafl, a drug rarely administered at the time of DFT testing, substantially increases DFT in swine.\(^{119}\)

Other Increases in Chronic DFT

As noted above, multiple factors may contribute to the lower first-shock success rate for spontaneous arrhythmias in the VF zone than for induced VF. A low implant DFT may protect against some factors that contribute to the lower success rate for spontaneous VT/VF. However, to date, evidence neither supports nor refutes this conjecture. The LESS study found no benefit of a very large programmed safety margin for low DFT patients, but it does not address the question of whether the shock success rate would be equivalent for patients with higher DFTs.\(^{52}\)

Advantages of a Lower Programmed First Shock Strength

Programming a low first-shock strength on the basis of a low patient-specific implant criterion minimizes the long-term adverse effects of excessive programmed shock strength. It reduces battery depletion if the ICD charges frequently for delivered or aborted shocks in the setting of “VT storm,” repetitive nonsustained VT, lead failure, or repetitive inappropriate detection of Supraventricular tachycardia (SVT). Post-shock depression of myocardial contractility depends on shock strength,\(^{111}\) and avoiding unnecessarily strong shocks may reduce this phenomenon. But most ICD shocks are programmed to maximum output, and it is not known if patient-specific programming reduces the incidence of fatal post-shock electromechanical dissociation.\(^{84}\) Because the time required to charge an ICD capacitor is longer for stronger shocks and increases as many ICDs age, the risk of syncope with resultant trauma may be lower when the first shock is programmed to a low patient-specific value rather than to maximum output. This consideration is less important for some modern ICDs that use anode-limited batteries, which permit charging to maximum output within 10 sec throughout service life. Nevertheless, programming a long duration to detect VF and a low patient-specific shock strength may be preferable in some patients with nonsustained VT/VF (e.g., long QT syndrome) to permit rapid therapy without aborted charges.

Factors that Influence Required Defibrillation Shock Strength—Predictable and Unpredictable

For convenience, we classify these factors into four groups: (1) patient-specific factors, (2) factors related to the ICD system (leads, shock waveform, defibrillation pathway), (3) drug effects, and (4) implant-related factors and complications (see Table IV).

Patient-Specific Factors

If DFT could be predicted by clinical variables, defibrillation testing could be restricted to a subset of patients. For this reason, multiple studies have attempted to identify patient-specific factors associated with high DFTs. Common, related correlates of higher DFTs are identified in multiple studies: (1) lower left-ventricular ejection fraction,\(^{51,88,96,120-122}\) greater left-ventricular size,\(^{96,123}\) or mass,\(^{125,126}\) and worse clinical heart failure;\(^{61,86,96,121-123,126}\) (2) male gender;\(^{61,86,96,120,123,126}\)
Factors related to the shock waveform, shock vector, and high voltage leads can be altered directly or indirectly at implant. Thus familiarity with their effects is important in the management of high DFT patients.

ICD System

Factors related to the shock waveform, shock vector, and high voltage leads can be altered directly or indirectly at implant. Thus familiarity with their effects is important in the management of high DFT patients.
reported with leads placed in the right-ventricular outflow tract\textsuperscript{143} or septum.\textsuperscript{144} Alternatively, a rate-sensing lead may be placed in a different right-ventricular location.

For fixed tilt waveforms, dual-coil leads reduce left pectoral DFTs by 10–20% compared with single coil leads, providing the proximal coil is positioned high enough to prevent shunting of current through the right atrial blood pool.\textsuperscript{105,145} The reduction in DFT provided by superior vena cava or subcutaneous electrodes may be due in part to shortening of fixed-tilt waveforms caused by reduced pathway resistance. Conversely, the advantage of dual-coil leads is less when waveform duration is optimized for pathway resistance of a single-coil lead.\textsuperscript{146} If the proximal coil must be positioned low in the atrium, it should be excluded from the circuit or a single coil lead should be used. An alternative to a dual-coil lead is a proximal coil on a second lead that can be positioned independently of the first lead, usually in the superior vena cava, innominate vein, or left subclavian vein.\textsuperscript{147} Less commonly, proximal coils are positioned in the coronary sinus, brachiocephalic vein\textsuperscript{8} azygous vein\textsuperscript{148} or inferior vena cava.\textsuperscript{144}

Right-sided pectoral implants require stronger defibrillation shocks than left-sided implants. The average increase in DFT is \(~50\%\)\textsuperscript{149,150} Anecdotal experience suggests that removing the pulse generator can from the pathway may reduce DFT in some right-sided implants. This may be accomplished either by using a pulse generator with an inactive can or (in only in one manufacturer’s ICD) by electronic programming. A coil electrode in the innominate vein may be especially useful in right-sided implants to provide a leftward shock vector.

A subcutaneous electrode\textsuperscript{151} or electrode array\textsuperscript{152} is the most effective of commonly used methods for reducing DFTs. Limitations include the need for deep sedation or general anesthesia during lead insertion; lack of experience of many operators with these leads; and potential long-term risks of infection, erosion, and chronic pain.

**Defibrillation Efficacy for Cardiac Resynchronization ICDs**

Data regarding DFTs in cardiac resynchronization patients are limited. One study reported DFTs comparable to those reported for other ICD patients in those cardiac resynchronization patients who were stable enough to undergo testing.\textsuperscript{153} In that study, 11% of patients were either not stable enough to undergo testing or had unacceptable DFTs. In another study, 9% of patients could not undergo defibrillation testing, and 12% of the remainder had high DFTs.\textsuperscript{154} QRS duration was the only predictor of a high defibrillation threshold.

**Drug Effects**

Drug-ICD interactions have been reviewed extensively.\textsuperscript{147,155–160}

**Antiarrhythmic Drugs**

Antiarrhythmic drugs are prescribed to 22–67% of patients with ICDs.\textsuperscript{52,147,160,161} Of these, the most widely studied is chronic oral amiodarone, which increases DFTs by 15–48% in unselected patients.\textsuperscript{114–118,162} A meta-analysis reported that amiodarone increased DFT by a mean of 35%, but it increased variance of DFT by 52%, thus having a disproportionate effect on patients with high DFTs.\textsuperscript{111} If the DFT is known to be low (\(\leq 15\) J), the risk of an increase sufficient to prevent defibrillation with maximum output is sufficiently low that repeat defibrillation testing is not required.\textsuperscript{115} However, if the defibrillation safety margin at implant is small or unknown, follow-up defibrillation testing is usually recommended after the loading phase of amiodarone therapy.\textsuperscript{163} Patients taking amiodarone are three times more likely to have high DFTs than patients not taking amiodarone.\textsuperscript{61}

In general, sodium channel blocking drugs increase DFTs.\textsuperscript{155,156} Lidocaine has a profound effect on DFTs.\textsuperscript{164,165} Its volume of distribution is reduced in heart failure, and its half life is markedly prolonged in the presence of inadequate hepatic perfusion or liver disease.\textsuperscript{166} It must be discontinued 3 to 5 half lives before defibrillation testing. Conversely, potassium channel blocking drugs (sotalol,\textsuperscript{167} dofetilide,\textsuperscript{167} and azimilide\textsuperscript{168}) reduce DFTs and have been prescribed to reduce high DFTs.

**Anesthetics**

Several studies have addressed the effect of modern anesthetics on defibrillation efficacy. A randomized, prospective study reported no difference in DFTs among patients treated with either isoflurane or propofol.\textsuperscript{169} Another study reported that defibrillation threshold was lower when implants were performed using local anesthesia with lidocaine followed by propofol for defibrillation testing than when they were performed using general anesthesia with either halothane, isoflurane, or fentanyl plus nitrous oxide.\textsuperscript{170} However, systemic concentrations of lidocaine and marked elevation of DFTs have been reported after use of lidocaine during ICD implantation.\textsuperscript{165} Lidocaine may be administered intravenously to reduce local pain at the propofol infusion site.\textsuperscript{171} It should not be infused with propofol immediately prior to defibrillation testing. Some implanters prefer bupivacaine to lidocaine for local anesthetic during ICD implantation. It provides longer analgesia and may have less of an effect on DFT.\textsuperscript{172} In addition,
anesthetics may have secondary effects on DFT related to myocardial depression, hypoxia, or hypercapnea.

Cardiac Drugs

Most beta blockers have no significant effect on DFT, but limited data indicate that carvedilol can increase DFT. Angiotensin converting enzyme inhibitors and angiotensin receptor blockers have no effects. Verapamil increases DFTs. It is prescribed to improve diastolic function in patients with hypertrophic cardiomyopathy and severe hypertrophy, who may independently be at risk for high DFTs.

Implant-Related Factors and Complications

If defibrillation is unsuccessful, high-voltage connections to the pulse generator should be checked. Inspection of routine tip-to-ring and high-voltage electrograms does not identify switched high voltage connections. Comparison of the electrogram between the can and right-ventricular coil with the electrogram between the can and proximal coil will identify a reversed connection if lead markings are hard to identify at generator replacement. Retained guide wires or fragments of old electrodes may shunt current away from the heart. Pleural or pericardial effusions also create parallel paths. Pneumothorax increases pathway resistance and DFT by placing insulating air in the current path. It may cause a marked increase in impedance between right-ventricular coil and pectoral can.

DFTs may be elevated by prolonged procedures or many VF episodes with insufficient intervening time for recovery. Related considerations include myocardial depression, ischemia, hypercapnea and acidosis. One clue that prolonged testing may be the problem is failure of a shock strength that defibrillated reliably earlier in the case.

Management of High DFT Patients

Management of the high DFT patient has been reviewed recently, including an excellent flow diagram. Our stepwise approach is summarized in Table V. Attention to steps that prevent high DFTs (Step 0) probably reduces the need to troubleshoot high DFTs. These include routine positioning of the distal defibrillation coil accurately in the right-ventricular apex (possibly against the septum) and routine use of a high-output ICD generator (at approx. 34 J). Before testing, confirm that high-voltage connections are correct and have nominal impedances measured by low-voltage pulses.

Before beginning to troubleshoot a high DFT, the diagnosis should be confirmed. Failure of a test shock at ≥20 J and a maximum output rescue shock is sufficient, if detection of VF is rapid and the charge time to maximum output is ≤10 s. But a single failed defibrillation can occur by chance alone. Thus, if a test shock fails but a maximum output shock succeeds, the test shock should be repeated, preferably with a measure related to ULV, such as scanning the T wave in paced rhythm with shocks at the test shock strength (see later). Unreliable defibrillation at the minimum desirable safety margin (commonly considered as 10-J below maximum output) should prompt an effort to improve defibrillation efficacy.

Once a high DFT is established, the first step is to identify and correct acutely reversible causes according to the check list in Step 1: Exclude ischemia, metabolic causes (including hypercapnea and acidemia which may occur after deep sedation in the absence of intubation), alternate current paths, and sources of increased resistance such as pneumothorax.

If the defibrillation system does not pass the implant criterion but the DFT is below maximum output, consider reprogramming the shock waveform if this is an option (Step 2). If this is unsuccessful or not an option, alter the transvenous shock vector if practical (Step 3). If altering the transvenous shock vector is impractical or unsuccessful, insert a subcutaneous electrode or array (Step 4). Inserting a subcutaneous array should be the first step if the DFT exceeds the maximum output of the ICD, since programming or alterations of a well-placed transvenous lead system are unlikely to produce a sufficient reduction in DFT.

At intervals, consider whether there may be a reversible factor that cannot be corrected acutely, such as myocardial depression, pharmacological effect, or left pleural effusion. If so, testing may be better performed on another day after the problem has been resolved. If no potentially reversible factors are present, consider an epicardial lead system (Step 5).

Assessing Defibrillation Efficacy Without Inducing VF

The ULV and Vulnerability Safety Margin

The ULV is the weakest shock strength at or above which VF is not induced when the shock is delivered during the vulnerable period. The ULV hypothesis of defibrillation postulates a mechanistic relationship between the ULV—measured during regular rhythm—and the minimum shock strength that defibrillates reliably. The ULV-DFT correlation has been validated in multiple animal and human studies. It remains strong and invariant, within experimental error, over a wide range of conditions. Clinically,
Table V.
Stepwise Approach to the Patient with High DFTs

<table>
<thead>
<tr>
<th>Step 0: Prevent High DFTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before implant: Consider risk/benefit of continuing or withdrawing drugs that may increase DFT</td>
</tr>
<tr>
<td>Optimize medical therapy of heart failure</td>
</tr>
<tr>
<td>Drain left pleural effusion</td>
</tr>
<tr>
<td>At Implant: Position RV electrode tip at apex (before testing)</td>
</tr>
<tr>
<td>Ensure appropriate position of proximal coil in high SVC or innominate vein; exclude proximal coil if low in atrium</td>
</tr>
<tr>
<td>Set right ventricular polarity to anode for phase 1 if not nominal</td>
</tr>
<tr>
<td>Optimize waveform duration for shock pathway impedance if programmable</td>
</tr>
<tr>
<td>Use a high-output generator (( \geq 34 \text{ J}) )</td>
</tr>
<tr>
<td>Confirm high-voltage connections</td>
</tr>
<tr>
<td>Correct connections of RV and SVC electrodes</td>
</tr>
<tr>
<td>Integrity of current paths (nominal impedance assessed by low-voltage pulses)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 1: Identify and Correct Acutely Reversible Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correctable at implant: Metabolic: hyperkalemia, hypoxemia, Ischemia</td>
</tr>
<tr>
<td>Alternates current paths: Left, pleural effusion or hemothorax; pericardial effusion or hern pericardium</td>
</tr>
<tr>
<td>Retained guide wire</td>
</tr>
<tr>
<td>Fragments of old intracardiac or intravascular electrodes</td>
</tr>
<tr>
<td>Pneumothorax</td>
</tr>
<tr>
<td>Not correctable at implant: Myocardial depression</td>
</tr>
<tr>
<td>Pharmacological (e.g., amiodarone, verapamil, lidocaine)</td>
</tr>
<tr>
<td>Prolonged procedure with multiple fibrillation-defibrillation episodes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 2: [Optional] Change Shock Waveform if Programmable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reprogram pulse durations for a different time constant</td>
</tr>
<tr>
<td>Chronic amiodarone: program shorter phase 2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 3: [If Defibrillation Succeeds at Maximum Output] Alter Transvenous Shock Vector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal coil in SVC, innominate vein, or high right atrium (exclude proximal coil if low)</td>
</tr>
<tr>
<td>Right-sided implant; exclude can* or use cold can</td>
</tr>
<tr>
<td>Add separate coil (e.g., innominate vein or left subclavian vein)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 4: Implant Subcutaneous Electrode or Electrode Array</th>
</tr>
</thead>
</table>

| Step 5: Consider Epicardial System |

---

Vulnerability testing can be applied to either a patient-specific strategy (which requires initiation of one VF episode) or to a safety-margin strategy. The latter has attracted interest because it permits assessment of defibrillation efficacy without inducing VF in 75–90% of ICD recipients. Clinical vulnerability safety-margin testing has been reviewed for details. Briefly, T-wave shocks are delivered at several coupling intervals to ensure that the most vulnerable part of the cardiac cycle is scanned. If VF is not induced, the shock strength exceeds the ULV, which approximates the shock strength associated with a 90% probability of defibrillation (E90). The ULV and DFT+52 have approximately equal shock efficacy. They are the only patient-specific shocks that has been shown to correlate with a specific point on the defibrillation probability of success curve in humans. Shocks programmed to 5 J above the ULV defibrillate induced VF acutely and chronically with near 100% success. Shocks programmed to 5 J above the ULV terminate spontaneous VT/VF at least as reliably as shocks programmed 10 J above the DFT. Shocks programmed in relation to a vulnerability safety margin terminate spontaneous VT/VF at least as reliably as shocks programmed in relation to a defibrillation safety margin. Because the ULV is more reproducible than the DFT, it provides greater statistical power for clinical research with fewer episodes of VF.

**Limitations of Vulnerability Testing**

1. Electrocardiogram (ECG) Equipment required: Presently, the vulnerability method requires recording 6–12 surface ECG leads at \( \geq 100 \text{ mm/sec} \) to determine the timing of T-wave shocks. It is impractical if \( \leq 3 \) ECG leads are recorded or if measurements can be made only at \( 25 \text{ mm/sec} \). In contrast, commercially available ICD programmers incorporate technology designed to induce VF for defibrillation testing, such as T-wave shocks, 50 Hz burst pacing, and direct-current stimulation.

2. Duration of anesthesia/deep sedation: Some implanters perform defibrillation safety-margin testing with one induction of VF (one or two shocks, depending on induction method). This can usually be performed more rapidly than vulnerability safety margin testing, which requires a minimum of 4 min of anesthesia or deep sedation. However, on occasion, VF can be difficult to induce, despite the multiple options provided by ICD programmers. In a recent multicenter study, the time required for vulnerability safety margin testing averaged 2 min more than that required for defibrillation safety margin testing. (3) Contraindications: Vulnerability testing is either contraindicated or not practical in about 5% of ICD recipients. It is...
contraindicated if the baseline, intrinsic rhythm is too slow to permit measurement of an R wave. Rarely, it is technically difficult if a stable paced rhythm cannot be achieved (e.g., frequent premature ventricular complexes or rapidly-conducted atrial fibrillation). In a recent large multicenter study of 426 patients, ULV testing was completed in 98.6% of patients while a single fibrillation-defibrillation episode was completed in 97.6%.

(4) Induction of VF. Depending on the shock strength used for T wave scanning, VF is induced in 14%–17% of patients. Using a 14–15 J shock strength, VF is induced in 14%–23% of patients. Thus vulnerability testing requires the same preparation for external, rescue defibrillation as defibrillation testing. (5) Vulnerability testing is subject to operator error.

**Risks of Assessing Defibrillation Efficacy at Implant**

The risks of DFT testing include those related to VF and those related to shocks alone. The former may be due to circulatory arrest alone or the combination of circulatory arrest and shocks, since VF is always shocked. Anesthesia required for delivery of shocks is another potential cause of complications. Table VII summarizes contraindications to implant testing.

**Risks of VF**

**Central Nervous System Hypoperfusion**

Intra-operative electroencephalographic (EEG) monitoring during DFT testing frequently shows EEG “slowing” consistent with cerebral ischemia. These changes may have a cumulative depressant effect on the EEG if repeated VF inductions are performed. Monitoring middle cerebral artery blood flow during VF inductions shows that cerebral oxygen uptake may be depressed for a following VF, especially after longer episodes that require multiple shocks. Cerebral blood flow may be depressed for several minutes after normalization of mean arterial pressure and EEG, particularly after repeated inductions of VF.

**Myocardial Ischemia and Electromechanical Dissociation**

In patients with coronary artery disease, hypotension due to prolonged episodes of VF may result in myocardial ischemia. Perioperative myocardial infarction is difficult to diagnose because routine defibrillation testing shocks delivered for spontaneous VT/VF or supraventricular tachycardia may cause both elevation of troponin and non-specific ECG changes. However, in an analysis of shocks for spontaneous arrhythmias, troponin elevations were both more likely and higher in patients with coronary artery disease than in those without, suggesting that the combination of VT/VF and shocks causes ischemic injury in some patients. Intraoperative myocardial infarction was reported in 1 of 84 patients (1%) in whom extensive DFT testing was performed. In patients with coronary stents, acute stent thrombosis is a potential consequence of VF-induced hypotension, but we are unaware of any reports of this complication.

As discussed below, both shocks alone and VF may depress contractile function. But, to the best of our knowledge, fatal electromechanical dissociation has been reported only after defibrillation from VF (unpublished). This distinction applies both during implant testing and follow-up. While post-shock electromechanical dissociation is a leading cause of sudden cardiac death in patients treated with ICDs, it has not been reported after inappropriate shocks. Some patients who suffered fatal electromechanical dissociation had severe left-ventricular dysfunction or underwent many fibrillation-defibrillation episodes, but electromechanical dissociation has also been reported in stable patients during the first fibrillation-defibrillation episode. Electromechanical dissociation probably is the most common cause of death related to defibrillation testing, occurring in about 0.1% of patients who undergo defibrillation testing at implant.

**Refractory VF**

One study reported that all tested ICD shocks failed and ≥3 external rescue shocks were required in 0.5% of patients. The incidence of death from refractory VF is unknown, but probably substantially less than 0.1%.

**Risks of Shocks Alone**

**Myocardial Depression from Shocks or VF**

Shocks alone may depress myocardial contractility, and the magnitude of shock-induced myocardial depression correlates with shock strength. However, the magnitude of myocardial depression is usually greater after the combination of fibrillation and defibrillation than after shocks alone. This is particularly true after long episodes of defibrillation, which can cause myocardial stunning and heart failure. Data regarding the incidence of clinically significant myocardial depression after defibrillation testing are limited. In an echocardiographic study, only 1 of 6 patients with depressed left ventricular (LV) function (28% ± 14%) had a significant change in left-ventricular ejection fraction (from
20% to 11%).

Another echocardiographic study of 12 patients found no significant impairment in left ventricular systolic function up to 1 hr after noninvasive fibrillation-defibrillation testing. A hemodynamic-monitoring study of 6 patients with left-ventricular ejection fraction < 30% reported a significant 27% decrease in cardiac index after fibrillation-defibrillation testing.

Thromboembolic Complications

Shocks may cause arterial thromboembolism if intracardiac thrombus is present. In patients with atrial fibrillation and left-atrial appendage thrombus, either T-wave shocks or defibrillation shocks may cause thromboembolism. This risk is analogous to the well-studied risk of thromboembolism associated with atrial cardioversion. Anticoagulation is typically discontinued before and after ICD implantation, potentially increasing the risk of left-atrial appendage thrombus formation in patients with atrial fibrillation. Left-ventricular thrombus may also be a source of thromboembolism in patients undergoing defibrillation implant testing. One study reported a thromboembolism incidence of 6.5% associated with defibrillation testing performed without systemic anticoagulation in patients with post-infarction, left-ventricular aneurysm, or dilated cardiomyopathy. Thromboembolism occurred despite the absence of a history of atrial fibrillation or documented intracardiac thrombus on preoperative transthoracic echocardiogram. This suggests a role for transesophageal echocardiography and/or anticoagulation in high-risk ICD patients. In contrast a retrospective study reported no thromboembolic complications in 21 patients who underwent elective or emergent cardioversion in the presence of left-ventricular thrombus.

Risks of Vulnerability Testing vs. Safety of Defibrillation Testing

Using either patient-specific or safety-margin strategies, vulnerability testing avoids the risks associated with VF or circulatory arrest in 75–90% of patients, including intractable VF, cerebral hypoperfusion, and myocardial ischemia. But vulnerability testing does not reduce risks caused by shocks alone or anesthesia. Both defibrillation and vulnerability testing can cause thromboembolism and transient myocardial depression. However, there is a higher probability of significant hypotension after a single fibrillation-defibrillation episode than after three T-wave shocks that do not induce VF (8% vs. 2%, P = 0.006). Further, fatal electromechanical dissociation has not been reported (or, to our knowledge, occurred) after T-wave shocks that did not induce VF. Prudence dictates that VF and circulatory arrest be induced only when they provide a specific benefit. Although defibrillation testing has a good safety record, vulnerability testing probably is safer (see Table VI).

Anesthesia-Related Complications

Anesthetic techniques for ICD implantation have been reviewed. Early ICDs were implanted using endotracheal intubation and general anesthesia with inhalational anesthetics such as isoflurane and nitrous oxide. Today, a commonly used technique is local anesthesia for insertion of leads and pulse generator combined with short-acting, deep intravenous sedation for defibrillation testing. This method reduces implant time and may reduce anesthesia-related complications.

Risks at Implantation of Cardiac Resynchronization ICDs

Patients undergoing implants of cardiac resynchronization ICDs are some of the sickest patients in whom defibrillation testing is considered, and they undergo some of the longest implant procedures. Testing of defibrillation efficacy may place some of these patients at risk for shock-induced dislodgment of passive coronary venous electrodes. Further, improvement in left-ventricular function by cardiac resynchronization pacing may reduce the DFT over time. It may be preferable to defer testing of defibrillation efficacy for 1–3 months for reasons relating to overall cardiac status, procedure duration, left-ventricular lead stability, or the likelihood of future reverse remodeling.

<table>
<thead>
<tr>
<th>Risks of Vulnerability Testing (Shocks Alone) vs. Defibrillation Testing (Shocks + VF) at ICD Implant Testing</th>
</tr>
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<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Defibrillation Testing</strong></td>
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<tr>
<td>---</td>
</tr>
<tr>
<td>Cerebral hypoperfusion</td>
</tr>
<tr>
<td>Myocardial ischemia</td>
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<tr>
<td>Prolonged circulatory arrest</td>
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<tr>
<td>Post-shock EMD</td>
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<tr>
<td><strong>Risks of Shocks Alone</strong></td>
</tr>
<tr>
<td>Thromboembolism if intracardiac thrombus</td>
</tr>
<tr>
<td>Ventricular dysfunction</td>
</tr>
<tr>
<td>Anesthesia required</td>
</tr>
</tbody>
</table>
Relative complications, but it requires careful monitoring of airway and ventilatory status. The most commonly used drugs are midazolam, fentanyl, and propofol. Etomidate has also been recommended because it has minimal or no effect on cardiac function. General anesthesia may be preferred in patients with Brugada syndrome in whom local anesthetics may be proarrhythmic and general anesthesia appears to be safe.

Anesthesia required for defibrillation testing may cause complications, particularly since many ICD recipients are high-risk candidates for anesthesia. Some anesthetics have a primary depressant effect on myocardial contractility. All anesthetics may have secondary effects if respiratory depression leads to hypoxia or hypercapnea. This may be more likely in patients with underlying lung disease or sleep apnea.

Operative Mortality

In spite of fewer inductions with improved technology, perioperative death may still occur. With current transvenous systems and biphasic devices, the perioperative mortality rate within 30 days of implantation has been reported to be 0.2–0.4%, but two series report a 0% mortality rate. We estimate that defibrillation testing causes about half of perioperative deaths. These risks must be weighed against the previously-discussed likelihood that sudden death (caused by failure to defibrillate or post-shock electromechanical dissociation after multiple failed shocks) can be prevented by implant testing.

Minimizing Risks

If shock testing is performed, the following safety guidelines should be followed:

- Perform a routine preoperative check including assessment of oxygenation, the airway, heart failure, and laboratory data including electrolytes.
- Ensure reliable external defibrillation: Test the external defibrillator and its connections to self-adhesive defibrillation electrode pads; confirm proper location of defibrillation pads.
- Assess the possibility of intracardiac thrombus. Use transesophageal echo if suspicion for left-atrial appendage thrombus is high. If atrial fibrillation is cardioverted inadvertently in a high-risk patient, consider re-fibrillating the atrium using the ICD’s atrial lead or a separate catheter.
- Anesthesia: A standard pre-anesthetic assessment should be performed prior to the procedure. If defibrillation testing is performed under intravenous sedation, the airway should be assessed preoperatively for potential difficulties of endotracheal intubation.
- Monitor intra-arterial pressure in patients with severe left-ventricular dysfunction and hypotension prior to anesthesia.
- Confirm sensing and pacing functions in baseline rhythm.
- Confirm integrity of the high-voltage leads by measuring lead impedance using low-voltage pulses. Proceed only if the impedance is in a range that excludes both a short circuit and an open circuit or inadequate lead connection (20–80 Ω).
- Wait between VF inductions: at least 1 min between shocks that do not induce VF and 4–5 min between shocks that induce VF. Recovery of cardiac output and cerebral perfusion lags recovery of arterial pressure by several minutes.
- Monitor respiratory status, including respiratory rate, tidal volume, oxygen saturation, and expired pCO₂. If acidosis is a concern, draw an arterial blood gas.
- If acute hypotension occurs, assess for acute reversible surgical complications (tension pneumothorax, hemothorax, pericardial tamponade); assess the ECG for ST segment changes or

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### Table VII.

<table>
<thead>
<tr>
<th>Contraindications to ICD Implant Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute</td>
</tr>
<tr>
<td>Risk of thromboembolism</td>
</tr>
<tr>
<td>Left-atrial thrombus</td>
</tr>
<tr>
<td>Left-ventricular thrombus without systemic anticoagulation</td>
</tr>
<tr>
<td>Atrial fibrillation without systemic anticoagulation*</td>
</tr>
<tr>
<td>Inadequate anesthesia or anesthesia support</td>
</tr>
<tr>
<td>Known inadequate external defibrillation</td>
</tr>
<tr>
<td>Severe aortic stenosis</td>
</tr>
<tr>
<td>Unstable angina</td>
</tr>
<tr>
<td>Severe, unrevascularized coronary artery disease with jeopardized myocardium</td>
</tr>
<tr>
<td>Hemodynamic instability requiring inotropic support</td>
</tr>
<tr>
<td>Relative</td>
</tr>
<tr>
<td>Left-ventricular mural thrombus with adequate systemic anticoagulation</td>
</tr>
<tr>
<td>Questionable external defibrillation (e.g., massive obesity)</td>
</tr>
<tr>
<td>Severe unrevascularized coronary artery disease</td>
</tr>
<tr>
<td>Recent coronary stent</td>
</tr>
<tr>
<td>Hemodynamic instability</td>
</tr>
<tr>
<td>Recent stroke or transient ischemic attack</td>
</tr>
<tr>
<td>Questionable stability of coronary venous lead</td>
</tr>
</tbody>
</table>

*Unless trans-esophageal echocardiography demonstrates no thrombus and anticoagulation initiated post-operatively.
other signs of ischemia; and assess for anesthetic or metabolic complications.

- After each shock, reassess the patient for hemodynamic effects and respiratory status. Determine if it is safe to proceed.

Operator experience: No discussion of risk would be complete without a comment regarding operator experience. Data regarding the relationship between complications of DFT testing and operator experience are limited. Until recently experienced electrophysiologists or teams of electrophysiologists and surgeons implanted all ICDs. In 2004, the Heart Rhythm Society developed guidelines describing an “alternative pathway” for training of non-electrophysiologist cardiologists to perform ICD implantation. Data regarding either the safety of defibrillation testing performed by these cardiologist implanters or the long-term efficacy of ICDs they implant has not been reported. We do not know if defibrillation testing performed by cardiologists with limited training will be as safe as testing performed by electrophysiologists with extensive training.

Noninvasive Post-Operative Testing of ICDs

Noninvasive post-operative testing of ICDs, either pre-discharge or a few months after implant is an alternative to testing at implantation. As noted previously, it may be preferred to implant testing in cardiac resynchronization ICDs. Post-operative testing has an excellent safety record. It is not influenced by some affect defibrillation efficacy at implant, it may be performed after contraindications to vulnerability or fibrillation-defibrillation testing have resolved, and it may identify problems that occur between implant and testing. But it is less convenient than intra-operative testing; and it adds cost to ICD therapy. Further, if the need for system revision is identified at noninvasive testing, a separate re-operation is required. With a few exceptions, most data regarding post-operative testing relates to its role as a supplement for intra-operative testing, rather than a substitute for it.

Recommendations and Perspective

The goal of implant testing is determine optimal balance between implant safety and long-term benefits of ICD therapy. Experts now consider testing less critical for left pectoral ICDs than they did 10 years ago. Sensing of VF is reliable if the R wave ≥ 5–7 mV. ICD generator failures are rare. Defibrillation is judged adequate by commonly-used safety-margin implant criteria in ~95% of patients. Low programmed first shock strength (intended to minimize risk of syncope) is less important because the incidence of spontaneous VT/VF

is lower, antitachycardia pacing terminates most episodes of rapid VT, and charge times are faster in most ICDs.

Conventional testing probably rejects <3% of prophylactic ICD patients correctly (true negative). Rigorous testing increases the fraction of true negative test results, but also increases implant complexity and risk. But most implanters, patients, and families have near zero tolerance for sudden cardiac death caused by preventable, failed defibrillation. Experts disagree about optimal implant testing because data are insufficient to define the optimal trade-off between accuracy and risk. Implant testing is in a state of evolution. The major trend is away from rigorous DFT testing and toward limited safety-margin testing or no testing. A minor trend is toward substitution of vulnerability testing for defibrillation testing. In this context, we offer the following considerations, which are illustrated in Figure 6:

Sensing and Detection of VF

If the R wave cannot be measured in baseline rhythm or atrial pacing or it is ≤5 mV, VF should be induced to ensure that undersensing does not
occur. If an additional cardiac electronic device is present, VF should be induced to exclude device–device interactions. In dual-chamber ICDs, programming specific parameters such as aggressive rate smoothing may require testing detection of VF to ensure that cross-chamber blanking periods do not cause undersensing. Overall, sensing and detection issues require induction of VF in about 5% of ICD recipients.

Defibrillation or Vulnerability Testing

One of these two methods should be used to assess a defibrillation safety margin if the a priori estimate of the shock strength required for reliable defibrillation is high. Examples include right-sided implants and amiodarone (see Table IV). The fraction of patients varies, but may range from 20% to 40%.

A patient-specific implant criterion should be used if long detection times are advisable in patients with frequent, long episodes of nonsustained VT/VF. Programming long detection times in combination with low shock strengths may prevent unnecessary aborted or delivered shocks while preventing syncopes with short charge times. This includes about 5% of ICD recipients.

Contraindications to Implant Testing

Table VII summarizes contraindications to implant testing. Of these, left atrial-appendage thrombus, inadequate anesthesia, and inadequate external rescue are absolute contraindications. Causing hypotension in a patient with a recent coronary stent is a weaker relative contraindication for vulnerability safety-margin testing than for defibrillation testing. Testing of a cardiac resynchronization ICD with questionable left-ventricular lead stability may be deferred or omitted because of the risk of post-shock LV lead dislodgement. A major contraindication to testing occurs in about 5% of ICD recipients, and a minor contraindication in 10–30%.

Legal and Regulatory Considerations

Presently, assessing defibrillation efficacy at implantation of ICDs is the legal standard of practice. The labeling on all U.S. manufactured ICDs recommends assessment of defibrillation efficacy at implant and programming the first VF shock with a 10-J safety margin. The Heart Rhythm Society also recommends implant defibrillation testing.220 If testing is not performed, we recommend documenting both the specific contraindication and whether or not post-implant testing is planned.

Relationship between Implant Testing and Training Requirement for Implanters

Training requirements for ICD implantation attract great interest because they may substantively affect whether, in the future, ICDs are implanted primarily by electrophysiologists with extensive training in defibrillation testing or primarily by cardiologists with limited or no training in defibrillation testing. Thus training requirements may have substantial influence on the number and qualifications of implanters. To the extent that more implanters result in more implants, training requirements may impact sales of ICDs. And to the extent that methods of implant testing (or no testing) influence training requirements, there is an implicit link between implant testing, who implants ICDs, and the economics of the medical device industry.227 While we acknowledge these broader implications of implant testing, the present review focuses on the optimal balance between implant safety and long-term benefits of ICD therapy. However, in analyzing results of future studies of implant testing, it may be useful to consider the interests of various stakeholders—electrophysiologists, cardiologists, industry, and the Heart Rhythm Society—when considering assumptions, methods, and funding.

Summary

VF should be induced to assess sensing in ~5% of ICD recipients. Defibrillation or vulnerability testing is indicated in 20—40% of recipients who can be identified as having a higher than usual probability of an inadequate defibrillation safety margin based on patient-specific factors. At least one maximum output shock should be delivered at the time of generator replacement. On the other hand, implant testing is too risky in ~5% of ICD recipients and may not be worth the risks in 10–30% more. In 25–50% of ICD recipients, implant testing cannot be identified as either critical or contraindicated.

References

ICD IMPLANT TESTING


A randomized, prospective, pair-sampled multicenter study (in press 2007).


